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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,845	07/15/2003	Yi Hu	LEX-0453-USA	2547
24231	7590	06/16/2004	EXAMINER	
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			MONSHIPOURI, MARYAM	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 06/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/620,845

**Applicant(s)**

HU ET AL.

**Examiner**

Maryam Monshipouri

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to isolated DNA molecules encoding a human kinase having SEQ ID NO:2, classified in class 536, subclass 23.2.
- II. Claims 4-5, drawn to isolated DNA molecules encoding a human kinase having SEQ ID NO:9, classified in class 536, subclass 23.2.
- III. Claim 7, drawn to isolated DNA molecules encoding SEQ ID NO:11, classified in class 536, subclass 23.2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I-III are patentably distinct each from the other because each invention is directed to a product of unrelated chemical structure and function.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Dr. P. Seferian on 5/24/2004 a provisional election was made without traverse to prosecute the invention of Group II, claims 4-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3 and 7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **DETAILED ACTION**

Claims 4-6 are under examination on the merits. Claims 1-3 and 7 are withdrawn as drawn to non-elected invention.

#### ***Priority***

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a .... of Application No. ...., filed ....." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included. It is noted that applicant refers to some priority data in the beginning of the specification. However, said reference is not complete. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA sequences comprising SEQ ID NO:8, does not reasonably provide enablement for isolated DNA sequences encoding at least 24 contiguous bases of SEQ ID NO:8.

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The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach about the structural and functional requirements of DNA sequences that merely comprise at least 24 bases of SEQ ID NO:8. No examples of such sequences are provided either. Current state of the prior art indicates that for a DNA sequence to encode a product with kinase activity it must at least comprise a region encoding the catalytic site of said kinase, which is, usually, of at least 250-300 amino acids (750-900 bases) in length. For said region to be within the scope of the specification, at least  $750-24=726$  additional bases, beyond the 24 bases in the claim, need to be identified.

Therefore due to lack of sufficient guidance and examples provided in the specification and due to unpredictability of the prior art as to what additional base residues must be incorporated into the DNA sequences that merely comprise at least 24 contiguous bases of SEQ ID NO:8, such that they encode a product with kinase function one of skill in the art has to go through the burden of undue experimentation in order to both make and use the products as claimed and as such the claim goes beyond the scope of the disclosure.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 4 as recited is directed to a **genus** of DNA sequences that have not been adequately described in the specification.

Claim 4 is directed to a genus of DNA that merely need to comprise at least 24 contiguous bases of SEQ ID NO:8 with no specific function. As stated above for a DNA sequence to encode a kinase it needs to comprise at least 750-900 bases corresponding to the catalytic site of said kinase. The specification does not teach about what those additional 726 bases ( $750-24=726$ ) must be and how they should be organized in a DNA sequence such that they encode a product with function. The specification teaches the structure of only a **single representative species** (SEQ ID NO:8) of such DNAs. Moreover, the specification fails to describe any other representative species by any identifying characteristics in terms of function and /or structure. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 4 is rejected under 35 U.S.C. 102(a) as being anticipated by Carninci et al. (Meth. Enzymol., 303, 19-44, July 1999). It is noted that applicant claims benefit of priority to provisional applications 60/199, 499 and 60/201,227. However, SEQ ID NO:8 has only been disclosed in the latter case which is filed on 5/1/2000. In view of said date, Carninci discloses a DNA sequence comprising at least 24 bases of SEQ ID NO:8 (see its residues 312-345 in the attached alignment) prior to this application, anticipating claim 4.

***Allowable Subject Matter***

Claims 5-6 are allowed. This is because DNA sequences encoding SEQ ID NO:8 are free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed DNA sequences, Hence said sequences are also non-obvious.

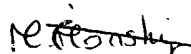
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Maryam Monshipouri Ph.D.

Primary Examiner

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